

Walk, Roger A.

From: Tricker, Anthony
Sent: Sunday, June 29, 2003 7:55 AM
To: Walk, Roger A.
Cc: Dempsey, Ruth
Subject: RE: RJR MS inhalation study on direct and indirect dried flue-cured tobaccos

DSS: Yes

The data was presented when you, Rick and I went to Boston to make presentations to the Massachusetts Tobacco Control Program (June 28th 2002). The results cast some doubt on the potential significance of a single class of compounds, in this case TSNA, on the biological significance of one class of compounds when present in a complex mixture. Below I have enclosed the notes I took and circulated on the RJR presentation.

Best regards,
 Tony

R.J. Reynolds (represented by James Swauger and David Iauco)

- Low-TSNA tobacco produced expected changes in mainstream smoke chemistry, but had no significant effect on genotoxicity (5 Ames tester strains), cytotoxicity (V79 cells), 90 day rat inhalation and Sencar mouse skin painting using a promotion protocol.
- Merit Ultra Light used as comparative brand in most of the in vitro Eclipse studies.
- Dallas test market for 'Eclipse' failed to capture meaningful market share (¼ share point).
- Smokers don't adjust to taste in favor of increased benefit.
- Consumer survey (1,000 smokers over 15 months) highlighted following attributes of 'Eclipse': less second-hand smoke (58%), less lingering odor (53%), and similar to other low-tar brands (41%).
- Stressed that public health standards will be necessary to generate smoker acceptance of new PREPs.

Discussion points and SAB observations:

- General disbelief that removal of TSNA had no measurable effects according to both in vitro assays and in vivo animal studies (in particular, both David Burns and Dietrich Hoffmann found results hard to believe).
- Determination of condensate TSNA recommended in genotoxicity studies (Dietrich Hoffmann).
- Very strong support for TSNA reduction (David Burns).
- Tell people to smoke less and leave longer butts. Use 'bulls eye test' to evaluate smoker behavior (Jack Henningfield).
- Reynolds criticized for not using the same commercial cigarette consistently as a point of reference during the assessment of 'Eclipse.' However, the data 'look good' and need a regulatory agency like the FDA to look at the data (Greg Connolly).

-----Original Message-----

From: Walk, Roger A.
Sent: Friday, 27. June 2003 14:18
To: Tricker, Anthony
Subject: Re: RJR MS inhalation study on direct and indirect dried flue-cured tobaccos

Tony:

When was this presented to MADoPH?

Is this relevant for assessing potential carcinogenicity of the test materials?

Roger Walk
Sent from my BlackBerry Wireless Handheld (www.BlackBerry.net)